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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,761	06/18/2001	Rolando Barbucci	1756	2132

7590 10/02/2002
Walter H Schneider
21530 Beechwood Road
Circleville, OH 43113

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/02/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,761	BARBUCCI ET AL.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 12-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 4 is objected to because of the following informalities: The formula set forth in Claim 4 is incorrect. The formula should be changed to " $[(CH_2)_n-O-(CH_2)_n]_m$ ". In Claim 14, line 3, the term "irom" should be changed to "iron". In Claim 16, line 4, the term 'seimi' is misspelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claim 3 recites the broad recitation "A is a C₂ – C₁₀ linear or branched alkylene chain", and the claim also recites "preferably a C₂ – C₆ chain" which is the narrower statement of the range/limitation.

In Claim 16, lines 3 and 4, the phrase "in solid or semi-solid form according to Claim 3" lacks clear antecedent basis since Claim 3 does not describe a substance having solid or semi-solid form.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-3, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Pouyani et al (US Patent No. 5,616,5680).

The Pouyani et al patent discloses covalently crosslinked derivatives of hyaluronate that is prepared by the attachment of a pendant hydrazido group on the hyaluronic acid backbone, which is within the scope of a diamine compound being attached to hyaluronic acid (see column 4, lines 47-49). See the 8th paragraph of column 4 wherein the Pouyani et al patent discloses that the coupling of aliphatic or aromatic diamines with hyaluronic acid using carbodiimides such as 1 ethyl-3-(3-dimethylaminopropyl carbodiimide is well known in the art. These diamines of the Pouyani et al patent anticipates the broadly claimed polyamine and diamine of instant Claims 1 and 2. The Pouyani et al patent also discloses adding dihydrazides to hyaluronate (see column 4, lines 66 and 67) whereby the dihydrazides may be represented by formula (II) (see the formula at column 5, line 6) wherein A may be a hydrocarbyl such as alkyl or aryl, or A is a heterohydrocarbyl which also includes

oxygen and nitrogen atoms in addition to carbon atoms. This dihydrazide of the Pouyani et al patent anticipate the diamine having the formula that is set forth in instant Claim 3 when "A" is a C₂ – C₁₀ linear or branched alkylene chain, substituted with carboxy and amino groups. See column 8, lines 19 and 20 of the Pouyani et al patent whereby it is indicated that the product thereof may be characterized as viscous or gel-like, which anticipates the gel form in instant Claim 13. The Pouyani et al patent further discloses that a crosslinked hyaluronate derivative may be utilized in pharmaceutical compositions (see column 2, lines 35-38), which can be used to treat osteoarthritis (see column 14, 1st paragraph), which anticipates instant Claim 15.

6. Claims 1-3 and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Prestwich et al (US Patent No. 5,874,417).

The Prestwich et al patent discloses crosslinked derivatives of hyaluronate that is prepared by the attachment of a dihydrazide represented by the formula (II) at line 45 of column 7 of the Prestwich et al patent wherein "A" is a hydrocarbyl such as alkyl and aryl or A is a heterohydrocarbyl which also includes oxygen and nitrogen atoms in addition to carbon atoms, which anticipates the broadly claimed diamines of the instant claims and the diamine of the formula set forth in instant Claim 3 when "A" is a C₂ – C₁₀ linear or branched alkylene chain, substituted with carboxy and amino groups. In column 2, lines 41-44, the Prestwich et al patent discloses the cross-linked hyaluronic acid in the form of a gel which anticipate instant Claim 13. Prestwich et al discloses that the hyaluronic acid thereof may be used as an aid in ophthalmic surgery and also as a potential therapy for osteoarthritis in humans, which anticipates Claims 15 and 16 of the instant application (see column 1, lines 38-42). Also see example 10 at column 22 of the Prestwich et al patent wherein a description of how metal ions effect the resulting properties of hydrazides when hyaluronic acid is formed in their presence. At line 66 and 67 of column 22, under Example 10, Prestwich et al discloses the metal ions as copper and iron, which anticipates instant Claim 14 when copper and iron is selected to form the metal complex of cross-linked hyaluronic acid.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-4 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prestwich et al (US Patent No. 5,874,417) in view of Galin et al (US Patent No. 5,944,753).

Applicants claim cross-linked hyaluronic acids obtainable by reaction of the carboxylic groups of hyaluronic acid and a polyamine.

The Prestwich et al patent discloses crosslinked derivatives of hyaluronate that is prepared by the attachment of a dihydrazide represented by the formula (II) at line 45 of column 7 of the Prestwich et al patent wherein "A" is a hydrocarbyl such as alkyl and

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aryl, or A is a heterohydrocarbyl which also includes oxygen and nitrogen atoms in addition to carbon atoms, which embraces the broadly claimed diamines of the instant claims and the diamine of the formula set forth in instant Claim 3 when "A" is a C₂ – C₁₀ linear or branched alkylene chain, substituted with carboxy and amino groups. The Prestwich patent further discloses that any of the carbon atoms of the alkyl group may be separated from each other with a configuration that may be selected as –O—CH₂—CH₂—O— (see column 7, line 65 to column 8, line 3), which embraces the polyoxyalkylene chain of the formula [(CH₂)_n-O-(CH₂)_n]_m that is set forth in instant Claim 3. In column 2, lines 41-44 the Prestwich et al patent discloses the cross-linked hyaluronic acid in the form of a gel which encompass the subject matter of instant Claim 13. Prestwich et al discloses that the hyaluronic acid thereof may be used as an aid in ophthalmic surgery and also as a potential therapy for osteoarthritis in humans, which embraces Claims 15 and 16 of the instant application (see column 1, lines 38-42). Also see example 10 at column 22 of the Prestwich et al patent wherein a description of how metal ions effect the resulting properties of hydrazides when hyaluronic acid is formed in their presence. At line 66 and 67 of column 22, under Example 10, Prestwich et al discloses the metal ions as copper and iron, which embraces the subject matter of instant Claim 14 when copper and iron is selected to form the metal complex of cross-linked hyaluronic acid. The cross-linked hyaluronic acids of the instant claims differ from the cross-linked hyaluronic acids of the Prestwich et al patent by further indicating that the hydroxy groups of the hyaluronic acid are sulphated or hemisuccinylated. The Galin et al patent shows that sulfated hyaluronic acid is well known in the art (see column 6, line 11). Also see example 2 of the Galin et al patent wherein a process step is disclosed whereby heparin (a sulfated polysaccharide) is coupled with a diamine. This process step of Example 2 of the Galin patent embraces the cross-linkage of the sulphated hyaluronic acid of the instant claims since the Galin et al patent teaches the substitution of heparin with sulfated hyaluronic acid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the hyaluronic acid used to form a cross-linked hyaluronic acid of the Prestwich et al patent with sulfated hyaluronic acid, in view of the recognition in the art, as evidenced by the Galin

et al patent, that sulfated polysaccharides such as sulfated hyaluronic acid improves the biocompatibility of implants in the anterior chamber of the eye.

Summary

9. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

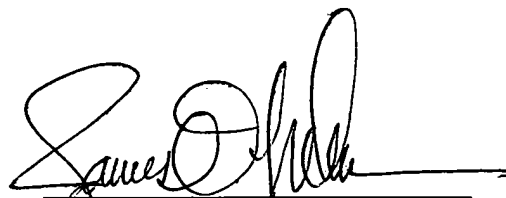
10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White



James O. Wilson
Supervisory Primary Examiner
Technology Center 1600